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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,295	COUNTER ET AL.	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9 and 11-23* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Invention 2 (claims 8-23) in the reply filed on 12/16/2008 acknowledged. The traversal is on the ground(s) that searching all the inventions can be made without serious burden. This is not found persuasive for reasons of record as restated below.

The inventions listed as Inventions 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-3 is a chimeric molecule comprising a polypeptide having telomerase catalytic activity fused to a telomere binding polypeptide. However, the reference of Evans et al. (Science. 1999 Oct 1;286(5437):117-20; reference of record) teaches such chimeric molecule.

Evans et al. teach a chimeric protein consisting of *S. cerevisiae* telomere binding protein Cdcl3 and telomerase or catalytic domain of telomerase, where the chimeric protein elongated chromosomes in *S. cerevisiae* cells. Evans et al. teach the encoding DNA, expression vector, and host cell. Evans et al. described, therefore, a method of producing the fusion protein and a method of elongating telomere length by a protein comprising a polypeptide having telomerase catalytic activity and a telomere binding polypeptide.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-3 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-7 and 24 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-23 are under consideration in this Office Action.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. Claim 8 is objected to for depending from nonelected claim 1. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. For examination purposes, it is assumed that claim 8 recites all the limitations of claim 1.

Claim Rejections - 35 U.S.C. § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 8-10 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8, 9, and 11-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are directed toward the current USPTO Written Description Training Materials made available to the public on 04/11/2008 for information regarding examination of patent claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph.

The claims are genus claims encompassing a genus of nucleic acids encoding polypeptides having telomerase catalytic activity fused to a telomere binding polypeptide where the said polypeptides are from any biological source having any amino acid sequences for which no structure is apparent, a genus of nucleic acids encoding functional portions thereof from any biological source having any amino acid sequences for which no structure is apparent, and a genus of nucleic acids encoding variants thereof from any biological source having any amino acid sequences for which no structure is apparent. The scope of each genus includes many members with widely differing amino acid and/or structures, where the genus is highly variable because a significant number of structural and biological differences between genus members exists. The specification, however, does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of each genus. The specification does not provide a correlation between any structure and enzymatic activity, such as telomerase activity.

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional nucleic acids encoding polypeptides having telomerase catalytic activity fused to a telomere binding

polypeptide, functional portions thereof, and variants thereof other than the isolated polynucleotide of SEQ ID NO: 1. As such the disclosure of the isolated polynucleotide of SEQ ID NO: 1 is insufficient to be representative of the attributes and features common to all the members of each claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the bovine sequence. In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the each genus. Dependent claims 9 and 11-23 are also rejected because they do not correct the defect of claim 8.

9. Claims 8, 9, and 11-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 1, a vector comprising said isolated polynucleotide comprising SEQ ID NO: 1, composition comprising said isolated polynucleotide comprising SEQ ID NO: 1, and an isolated cell comprising said isolated polynucleotide comprising SEQ ID NO: 1; **does not** reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The

quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass any nucleic acid encoding polypeptides having telomerase catalytic activity fused to a telomere binding polypeptide where the said polypeptides are from any biological source having any amino acid sequences for which no structure is apparent, any nucleic acid encoding functional portions thereof from any biological source having any amino acid sequences for which no structure is apparent, and any nucleic acids encoding variants thereof from any biological source having any amino acid sequences for which no structure is apparent.

The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teaches that the complexity of the structure/function relationship in enzymes has proven to be the factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships. The reference of Sen et al. (Appl Biochem Biotechnol. 2007 Dec;143(3):212-23; PTO 892) teaches *in vitro* recombination techniques such as DNA shuffling, staggered extension process (StEP), random chimeragenesis on transient templates (RACHITT), iterative truncation for the creation of hybrid enzymes (ITCHY), recombined extension on truncated templates (RETT), and so on have been developed to mimic and accelerate nature's recombination strategy However, such directed evolution techniques only enable methods for searching and screening for the claimed nucleic acids.

The specification provides guidance, prediction, and working examples for an isolated polynucleotide comprising SEQ ID NO: 1, a vector comprising said isolated polynucleotide

comprising SEQ ID NO: 1, composition comprising said isolated polynucleotide comprising SEQ ID NO: 1, and an isolated cell comprising said isolated polynucleotide comprising SEQ ID NO: 1. However, the specification does not provide guidance, prediction, and working examples for making and using the nucleic acids as claimed. The specification does not provide a correlation between any structure and function, other than SEQ ID NO: 1 encoding a polypeptide having telomerase catalytic activity fused to a telomere binding polypeptide. Consequently, there in no information about the particular structures and amino acid sequences of the claimed "functional portion or variant thereof" that have telomerase catalytic activity and telomere binding activity.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for the claimed nucleic acids. Alternatively, trial and error experimentation involves making amino acid substitutions, deletions, additions, and combinations thereof to the polypeptide encoded by SEQ ID NO: 1 to make the recited functional portion or variant thereof, and searching and screening for polypeptides that still have telomerase catalytic activity and telomere binding activity. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention. Dependent claims 9 and 11-23 are also included in the rejection because these claims do not correct the defect of claim 8.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 8, 11, 12, 17, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (Science. 1999 Oct 1;286(5437):117-20; reference of record)

Evans et al. teach a chimeric protein consisting of *S. cerevisiae* telomere binding protein Cdcl3 and telomerase or catalytic domain of telomerase, where the chimeric protein elongated chromosomes in *S. cerevisiae* cells. Evans et al. teach the encoding DNA, expression vector, and host cell. Evans et al. described, therefore, a method of producing the fusion protein and a method of elongating telomere length by a protein comprising a polypeptide having telomerase catalytic activity and a telomere binding polypeptide. See entire publication especially Figs. 1-3. Thus, the reference teachings anticipate the claimed invention.

Conclusion

12. No claim is allowed.

13. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652